PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Michael DiCuccio, Richard L. Cunningham, Greg Merril, J. Michael Brown, Hugh Connacher, Philip Feldman, Joe Tasto	Confirmation No.	2152
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Docket No.:	1023-312US01		
Title:	INTERACTIVE COMPUTER MODEL OF THE HEART		

DECLARATION UNDER 37 C.F.R. 1.131

Commissioner for Patents
Washington, D.C. 20231

I, Richard L. Cunningham, declare as follows:

1. I am a named inventor in above-referenced patent application serial no. 09/839,638.

2. As evidenced by this Declaration and the Exhibits referenced by this Declaration, I conceived the inventions set forth in claims 10-15 of this application prior to March 6, 2001, and reduced the inventions set forth in claims 10-15 to practice prior to March 6, 2001.

Conception

3. Exhibits A and B, attached to this Declaration, contain documents that were prepared prior to March 6, 2001.

4. Exhibits A and B provide evidence of my conception of the inventions set forth in claims 10-15 prior to March 6, 2001.

5. Exhibit A is a true and accurate copy of an electronic version of a document prepared prior to March 6, 2001, by a design team of which I was a member. Exhibit A was archived on or about December 3, 1999. Exhibit A describes the characteristics and features of an interactive heart model conceived and developed by our design team and reduced to practice prior to December 3, 1999. Exhibit A describes a computer-simulated heart model that can be used in a surgical procedure. Exhibit A includes the following:

> There are many physiologic aspects of the heart to consider when attempting to create an extensible, generalized model of the heart for use in simulating medical procedures. First and foremost of these is completeness. The model should be as complete as possible, modelling [sic] all aspects of heart motion and function. To accurately simulate procedures such as cardiac catheterization (left and right), pacemaker placement, and flow dynamics inside the heart, we need to examine two main components of the heart: deformation and electrical characteristics.

6. Exhibit B is a true and accurate copy of an electronic version of a document I prepared prior to March 6, 2001 to identify and document certain elements of the design and invention of a system the design team at that time described as the "Medical Device Designer's Workbench." Exhibit B was archived on or about December 6, 1999. Exhibit B describes, among other things, a method or "mode of usage" of that system called "simulation based design." Exhibit B includes the following:

In this mode, a skilled practitioner or other user attempts a procedure using a simulation system simulating use of a particular tool, such as wire or catheter, with physical parameters such as shape, stiffness, torsional rigidity, ant [sic] the like that can be varied along the length of the device, or in response to temperature, time or some other method or means. The user is presented with materials views and editors in which the various properties can be varied to evaluate their effects on the ease of execution or the procedure, or the effect on procedural outcomes. For example, the viewer and editor for a stylet used to steer a heart pacing lead might consist of a graphical display of a model of the wire, with materials properties at various points along the wire represented accompanying line or bar graphs, or directly on the wire itself by means of color or other graphical means. A modal editor is used to modify parameters along the length or the device. The editor allows the user to specify which parameter or parameter is being altered, then enables setting values for that parameter at particular points along the length of the device. The editor can optionally interpolate materials properties between user set points, or can be used in full manual mode. Parameters that can be set at any point along the length of the device would include but not be limited to the following:

* Rest angle, angle of bend
* Stiffness, resistance to bending
* Torsional rigidity, resistance to twisting
* Viscosity or ductility
* Frictional characteristics, smoothness, roughness
* Temperature or time varying behavior

The practitioner would use the editors to modify the device in advance or and during the simulated procedure, observing the efficacy of various modifications and thus greatly speeding the design process.

7. In view of the content of Exhibits A and B, including the passages discussed above, it is clear that I conceived and was in possession of the inventions defined by at least claims 10-15 prior to March 6, 2001. With respect to independent claim 10, for example, Exhibits A and B contemplate a method of designing a surgical instrument as recited in claim 10. The method includes creating a computer model of the surgical instrument, such as wire or catheter. The method further includes using the model of the surgical instrument in a surgical simulation, such as a simulation of a cardiac catheterization procedure. The method further includes changing the computer model of the surgical instrument, such as changing shape, stiffness, torsional rigidity or other parameters. The method also includes using the changed model in a surgical simulation, during which the efficacy of various modifications can be observed. Accordingly, as demonstrated by Exhibits A and B, I conceived the inventions of claims 10-15 prior to March 6, 2001.

Reduction to Practice

8. Exhibits A and B further demonstrate that the invention was reduced to practice prior to March 6, 2001. The model described in Exhibit A refers to working prototype and Exhibit B refers to features that were designed for inclusion in the existing computer simulation. At the time of creation of Exhibits A and B, the prototype was able to carry out the steps in independent claim 10, namely creating a computer model of the surgical instrument, using the model of the surgical instrument in a surgical simulation, changing the computer model of the surgical instrument, and using the changed model in a surgical simulation. Furthermore, the parameters of a changed or second version of the surgical instrument could be used for manufacturing the instrument, as recited in independent claim 14. Accordingly, as demonstrated by Exhibits A and B, the inventions of claims independent claims 10 and 14 were reduced to practice prior to March 6, 2001.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 4 Feb 2004 Signed: _____
Richard L. Cunningham